

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR
WARMING PRODUCTS LIABILITY
LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:
All Cases

**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE
OPINIONS OF GARY SETTLES, PH.D.**

INTRODUCTION

Dr. Settles's Schlieren study has nothing to do with the movement of bacteria in the operating room. It cannot help a jury understand that issue, because Settles focuses solely on air. Air molecules do not cause infection; bacteria-laden particles do. Dr. Settles and 3M's other experts agree that particles do not necessarily follow air flows. Especially the 10 micron sized particles that carry colony forming units (CFUs) to the surgical site.

Dr. Settles himself conceded that Schlieren does not inform particle movement. If this were a case about air, his testimony might be relevant. But it is not a case about air. This is a case about bacteria-laden particles stirred up by Bair Hugger that migrate to the surgical site and cause devastating periprosthetic deep joint infection (PDJIs).

Despite the undisputed focus of this case, 3M continues to offer testimony that has nothing to do with bacteria. 3M's campaign to conflate air flow and bacteria movement harkens to a long-lost era. In 1881, President James Garfield was shot in the back by Charles Guiteau. As described in the New York Times bestseller, "Destiny of the Republic," President Garfield probably would have survived but for the "care" of his physicians.¹ Those physicians rejected then-new "germ theory" and the antiseptic advice of Dr. Joseph Lister that had already revolutionized operating rooms in England. President Garfield's doctors rejected the idea that tiny, invisible particles cause infection and instead focused on "bad air," or "miasma," while neglecting antiseptic hand-washing that had revolutionized operating rooms across the pond. While quaintly outdated, the

¹ Candice Millard, *Destiny of the Republic: A Tale of Madness, Medicine and the Murder of a President* (2011).

idea of focusing on mere ðmiasmaö apparently finds new life in 3Mö expert reports, all of which ask the jury to ignore actual analysis of particle flows in favor of mere air.

ARGUMENT

I. Settles' Expertise Does Not Qualify Him To Offer The Disclosed Opinions

The qualifications of an expert witness are necessarily contextual, such that an expert who is qualified in one field may not necessarily be an expert in a different field. *See Wheeling Pitts. Steel v. Beelman River Terminals*, 254 F.3d 706, 716 (8th Cir. 2001) (reversing district courtö admission of testimony where expert was qualified in one subject matter but not qualified by ðknowledge, skill, experience, training, or educationö in another subject area). Here, Settlesö fifty years of experience with Schlieren testing does not satisfy Rule 702ö qualification requirements for opinions that are outside of that narrow area of expertise. Plaintiffs elicited admissions through cross examination that certain subject matters are outside the area of Settlesö expertise, including both particle movement and CFD.² Given 3Mö failure to establish qualifications beyond the narrow Schlieren experiment, it would be error to admit any testimony from Dr. Settles relating to particles, particle movement, bacteria, operating rooms, infections, or otherwise.

A. Settles Disclaimed Expertise in Particle Movement

No one disputes that Settles is an expert in the Schlieren technique. But no one has shown how or why Schlieren would help any factfinder understand or decide a disputed issue in this case. Despite Defendantsö criticism of Plaintiffs for not offering an airflow experiment (Defö Opp. at 9-10), everyone agrees that this is a case about

² See DX2 (Settles Dep. at 87:19-24; 88:21).

particles, not mere airflow. It is (or should be) undisputed that patients do not get PJI from airflow; they get PJI from bacteria. Multiple witnesses on both sides of the ÷vs.÷ in this case have testified that particles floating around the OR carry bacteria.³

Bair Hugger causes those bacteria-laden particles to move to the surgical site. That particle movement is what Dr. Elghobashi simulated on a supercomputer. Not one of 3M's experts conducted any rebuttal experiment, simulation, or study.⁴ Despite knowing for years that this case was about particles of bacteria, Defendants have claimed privilege over their own internal CFD studies and relied solely on air flow experts instead of particle flow experts. Their steadfast refusal to face this issue head-on speaks volumes.

That Settles has been working with Schlieren for half a century does qualify him as an expert for all the topics for which 3M has offered his testimony. In particular, Settles disclaimed expertise in particles. His testimony was unequivocal:

“I’m not a particle expert.”⁵

Despite that concession, Defendants insist on arguing, without a single citation to evidence, that Schlieren can ÷illuminat[e] where particles can go.÷ (Def's Opp. at 15). That invites error. Settles himself cautioned against assuming particles merely follow air currents.⁶ That is not surprising, given that Settles unequivocally disqualified the use of

³ See, e.g., Doc. #874, DX2 (Wenzel Dep. 50:2-23).

⁴ Even Dr. Abraham's CFD was completed in early 2016, before the first status conference was held in this MDL. See Doc. #934, DX2 (Abraham Dep. at 25:1-25).

⁵ DX2 (Settles Dep. at 88:21)(emphasis added).

⁶ *Id.* at 90:6-17.

Schlieren for particle flow: it's not an appropriate instrument to measure particle flow.⁷ He went further, explaining that we made no attempt to track particle flow.⁸

Basically, 3M wants to use testimony from an expert who agrees that his technique is inappropriate for evaluating particle movement to confuse a jury into believing that particles nevertheless follow air flows. Not a single 3M expert provides the evidentiary hook for that theory. In that sense, it is even further removed from evidentiary support than the "analytical gap" in *Gen Elec. v. Joiner*; 3M does not even have an expert who will testify that air flows can approximate particle movement for the 10 micron particles in dispute. 522 U.S. 136, 146 (1997). 3M's unsupported effort to confuse the jury by equating air flows with particle movement should be rejected.

Defendants likewise argue that Settles should be allowed to testify about the benefits of a thermal plume, which they argue protects a patient from particles settling in the surgical site. (Def's Opp. at 7). But surely Settles cannot offer that testimony, given his concession under oath that he is not an expert in particle flow.⁹ The thermal plume theory inherently requires particle movement expertise—it is a theory that the thermal plume above a patient causes particles to move away from the surgical site.

3M's arguments highlight the reason why Settles's testimony is more likely to confuse the jury than to properly inform their decision. 3M criticizes the use of helium-

⁷ *Id.* at 59:4-18.

⁸ *Id.* at 59:22.

⁹ *Id.* at 117:1-2. Nor is Settles an expert in infectious disease, virology, or bacteriology. His human cough report was co-authored by a virologist. Settles has no qualifications to offer testimony beyond Schlieren imaging of air flows.

filled bubbles in the McGovern, Legg, and Belani articles, arguing that those bubbles “distort the flow field with their own momentum and direction.” (Def’s Opp. at 5). But Settles’ own expert report explains that Schlieren is more accurate than those techniques for “revealing true thermal *airflow* patterns.”¹⁰ Again, this case is not about “true thermal *airflow* patterns,” it is a case about bacteria-laden particles migrating to the surgical site because of Bair Hugger. As the very next line in Settles’ report states, “particles in an airstream have inertia and therefore **do not always follow the streamlines of the flow.**”¹¹ Defendants’ expert Dr. Kuehn agrees; he testified that an airstream can predict particle movement only when the particles are less than one micron.¹² Even Dr. Abraham agrees particles have mass and inertia and therefore fall out of flow.¹³ There is no dispute that the particles at issue in this case - the ones that carry CFUs into the surgical site - are ten microns or larger.¹⁴

3M offers no explanation for why a witness who expressly disqualified himself from testifying about particle movement should be nevertheless allowed to testify about particle movement, or even to offer testimony about air flows that will cause a jury to erroneously believe that those air flows inform particle movements. Dr. Settles’ testimony and opinions in this regard should be excluded.

¹⁰ See Ex. A to Doc. #834 (Settles Rep. at 3)(emphasis added).

¹¹ *Id.* (emphasis added).

¹² See Ex. E to Doc. #823 (Kuehn Dep. at 195:16-25).

¹³ See Doc. #934, DX2 (Abraham Dep. 227:14-230:8).

¹⁴ See, e.g., Noble, Wc, Lidwell, Om, Kingston, D et. al., *The size distribution of airborne particles carrying micro-organisms*, J HYG (Lond 1963) 61 (385), e391.

B. Settles Is Not An Expert In CFD

Defendants defend Settles's testimony rebutting Dr. Elghobashi's CFD analysis, but admit in their brief that "Dr. Settles is an expert in *experimental* fluid dynamics, not computational fluid dynamics." (Defs. Opp. at 12)(emphasis in original). Their own brief concedes that Settles is not qualified to offer an expert opinion on Dr. Elghobashi's CFD simulation. Rule 702 allows for opinion testimony from "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education." It contains no exception to the qualification requirement for rebuttal testimony. 3M and Settles have both conceded that Settles is not being offered as a CFD expert in this case.¹⁵ Because Settles is not qualified to offer opinions related to CFD, his rebuttal of Dr. Elghobashi should be excluded.

II. Settles Hot Dog Testimony Should Be Excluded

Allowing Settles to testify about Hot Dog would open a collateral dispute that would substantially complicate the case without directly informing any fact in dispute. Per this Court's Order, and following extensive briefing by Defendants, Plaintiffs are foreclosed from relying on Hot Dog or other conductive warming blankets as reasonable alternative designs.¹⁶ Having successfully kept certain competing products out of this case, Defendants now seek to admit testimony about those very products. It would be fundamentally unfair to allow Defendants to introduce evidence relating to Hot Dog

¹⁵ See Defs's Opp. at 12; DX2 (Settles Dep. at 87:19-24).

¹⁶ Plaintiffs respectfully maintain that the exclusion of conductive blanket technologies, including the Hot Dog and the VitaHeat, as reasonable alternative designs was an error.

while at the same time barring Plaintiffs from relying on such a device as a reasonable alternative design.

3M's creative explanation does not carry water. Settles offered no evidence that would explain the McGovern publication's findings, nor has 3M offered any rationale for why Dr. Settles's opinions would help the jury understand 3M's or Plaintiffs's interpretations or applications of the cited publications. Nowhere has 3M tied its epidemiological or any other analysis of McGovern's article to Settles's Schlieren test results. Settles made no effort to replicate the conditions of the McGovern or other papers. There is simply no basis to apply Settles's findings to those publications. Even if there were, given that Plaintiffs are precluded by Order of this Court from arguing that Hot Dog is a reasonable alternative design, Settles's Hot Dog tests do not meet Rule 702's requirement that testimony will help the jury understand or decide the disputes in the present case.

CONCLUSION

Settles offered wide-ranging opinions and conclusions that far exceed his narrow area of expertise. Defendants have offered no grounds upon which any of Settles's other opinions could be admitted. Settles's opinions about infection sources and particle movement are, by his own admission, outside of his areas of expertise and should therefore be excluded.

Respectfully submitted,

Dated: October 17, 2017

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